

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

March 5, 2015

Biolase Incorporated Ms. Colleen Boswell Vice President of Regulatory Affairs and Quality Assurance 4 Cromwell Irvine, California 92618

Re: K141975

Trade/Device Name: Waterlase iPlus S Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and

plastic surgery and in dermatology

Regulatory Class: Class II Product Code: GEX Dated: February 4, 2015 Received: February 6, 2015

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S. Director Division of Surgical Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number *(if known)* K141975

Device Name Waterlase iPlus S

Indications for Use (Describe)

The Waterlase iPlus S is intended for use as a laser surgical instrument in the following medical specialties requiring the incision, excision, vaporization, ablation and coagulation of soft tissue: Dermatology/Plastic Surgery, Ear, Nose and Throat (ENT), Gastroenterology, General Surgery, Genitourinary/Urology, Gynecology, Ophthalmology, Oral/Maxillofacial Surgery, Podiatry, Pulmonary Surgery and Thoracic Surgery. It is indicated for the following expanded Indications for Use:

Dermatology/Plastic Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking of begin tumors, decubitis ulcers, cysts, diagnostic biopsy and skin resurfacing and treatment of wrinkles.

Ear, Nose and Throat (ENT):

The following indications can be used with the Angled or Straight Handpieces:

ENT surgery in soft, mucosal, cartilaginous and bony tissue, including endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasias, septoplasty, lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.

Gastroenterology:

The following indications can be used with the Angled or Straight Handpieces:

Gastroenterologic surgery of soft tissue, including cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

Genitourinary/Urology:

The following indications are used with the Angled Handpieces:

Genitourinary surgery of soft tissue, including treatment of bladder, urethral and ureteral tumors, superficial urinary bladder tumors, invasive bladder carcinomas, urethral and penile hemangioma, urethral strictures, lesions of the external genitalia, urethra and anus, penis, scrotum, (includes condyloma acuminate, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon, bladder neck obstructions.

The following indications are used with the Straight Handpieces:

Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and

resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.					
Gynecology:					
The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:					
Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.					
Ophthalmology:					
The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:					
General ophthalmic soft tissue surgical indications such as: Incision, excision, vaporization and coagulation of ocular issue and tissue surrounding the eye and orbit.					
Oral/Maxillofacial Surgery:					
The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:					
Oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties,					
gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.					
Podiatry:					
The following indications can be used with the Angled or Contra-Angled Handpieces:					
Warts, plantar verrucae, large mosaic verrucae and matrixectomy.					
Pulmonary Surgery:					
The following indications can be used with the Angled or Straight Handpieces:					
Open and endoscopic pulmonary surgery.					
Thoracic Surgery:					
The following indications can be used with the Angled or Straight Handpieces:					
Surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.					
Type of Use (Select one or both, as applicable)					
Prescription Use (Part 21 CFR 801 Subpart D)					

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter:

Biolase, Inc. 4 Cromwell Irvine, California 92618 (949) 226-8470 - Phone (949) 273-6688 - Facsimile Alicia Mszyca - Contact Person

Date Summary Prepared: February 2015

- Trade Name Waterlase iPlus S
- Common Name Er,Cr:YSGG Laser
- Classification Name Laser surgical instrument for use in general and plastic surgery and in dermatology, per 21 CFR 878.4810
- Product Code GEX

Devices for Which Substantial Equivalence is Claimed:

- Oculase MD, Biolase, Inc., K052354
- Waterlase MD Derm, Biolase, Inc., K071734
- Profile Multi-Platform System, Sciton, Inc., K060033
- Laserscope VELA Erbium:YAG Laser System and Accessories, Laserscope, K971843

Device Description

The *Waterlase iPlus S* system is an erbium, chromium, yttrium, scandium, gallium, garnet (ER,CR:YSGG) solid state laser that provides optical energy to the user-controlled distribution of atomized water droplets at 2.78 µm (2780 nm). The laser consists of a cabinet which houses the power supply, the cooling system, micro-controller, laser, foot switch, and fiber optic for delivery of laser energy with the fiber optic handpiece. Various handpiece and tip types are available depending upon the clinician's preference for the different applications. The *Waterlase iPlus S* system utilizes direct laser energy either with or without water for cooling and hydration to perform soft tissue incision, excision, resection, ablation, vaporization, coagulation and hemostasis.

Statement of Intended Use

The Waterlase iPlus S is intended for use as a laser surgical instrument in the following medical specialties requiring the incision, excision, vaporization, ablation and coagulation of soft tissue: Dermatology/Plastic Surgery, Ear, Nose and Throat (ENT), Gastroenterology, General Surgery, Genitourinary/Urology, Gynecology, Ophthalmology, Oral/Maxillofacial Surgery, Podiatry, Pulmonary Surgery and Thoracic Surgery. It is indicated for the following expanded Indications for Use:

Dermatology/Plastic Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking of begin tumors, decubitis ulcers, cysts, diagnostic biopsy and skin resurfacing and treatment of wrinkles.

Ear, Nose and Throat (ENT):

The following indications can be used with the Angled or Straight Handpieces:

ENT surgery in soft, mucosal, cartilaginous and bony tissue, including endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasias, septoplasty, lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.

Gastroenterology:

The following indications can be used with the Angled or Straight Handpieces:

Gastroenterologic surgery of soft tissue, including cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

Genitourinary/Urology:

The following indications are used with the Angled Handpieces:

Genitourinary surgery of soft tissue, including treatment of bladder, urethral and ureteral tumors, superficial urinary bladder tumors, invasive bladder carcinomas, urethral and penile hemangioma, urethral strictures, lesions of the external genitalia, urethra and anus, penis, scrotum, (includes condyloma acuminate, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon, bladder neck obstructions.

The following indications are used with the Straight Handpieces:

Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecology:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:
Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Ophthalmology:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces: General ophthalmic soft tissue surgical indications such as: Incision, excision, vaporization and

coagulation of ocular tissue and tissue surrounding the eye and orbit.

Oral/Maxillofacial Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.

Podiatry:

The following indications can be used with the Angled or Contra-Angled Handpieces:

Warts, plantar verrucae, large mosaic verrucae and matrixectomy.

Pulmonary Surgery:

The following indications can be used with the Angled or Straight Handpieces:

Open and endoscopic pulmonary surgery.

Thoracic Surgery:

The following indications can be used with the Angled or Straight Handpieces:

Surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.

Summary of Technological Characteristics

Refer to the Table on the following pages.

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
Company	Biolase, Inc.	Biolase, Inc.	Biolase, Inc.	Sciton, Inc.	Laserscope
Indications for	The Waterlase iPlus S is	The Oculase MD	Use of the device	2940nm Indications	The Laserscope
Use	intended for use as a	may be indicated for	is indicated for	for Use:	VELA Erbium:YAG
	laser surgical instrument	general ophthalmic	the incision,	The Profile Multi-	Laser System and
	in the following medical	soft tissue surgical	excision, ablation,	Platform and	Accessories are
	specialties requiring the	indications such as:	vaporization and	Accessories are	intended for the
	incision, excision,	Incision, excision,	coagulation of	designed for use in	surgical
	vaporization, ablation	vaporization and	dermatologic	surgical applications	incision/excision,
	and coagulation of soft	coagulation of	tissues including	requiring the	vaporization and
	tissue:	ocular tissue and	epidermal nevi,	excision, incision,	coagulation of soft
	Dermatology/Plastic	tissue surrounding	cheilitis, keloids,	ablation,	tissue. All soft
	Surgery, Ear, Nose and	the eye and orbit.	verrucae, skin	vaporization, and	tissue is included,
	Throat (ENT),		tags, keratosis,	coagulation of soft	such as skin,
	Gastroenterology,		scar revision,	tissue, and for skin	subcutaneous
	General Surgery,		debulking of	resurfacing. Soft	tissue, striated
	Genitourinary/Urology,		tumors, cysts,	tissue includes skin,	and smooth
	Gynecology,		diagnostic biopsy	subcutaneous	tissue, muscle,
	Ophthalmology,		and skin	tissue, striated and	cartilage
	Oral/Maxillofacial		resurfacing.	smooth tissue,	meniscus, mucous
	Surgery, Podiatry,			muscle, cartilage,	membrane, lymph
	Pulmonary Surgery and		Use of the device	cartilage meniscus,	vessels and nodes,
	Thoracic Surgery. It is		is further	calculi or fragments,	organs and glands.
	indicated for the		indicated for the	mucous membrane,	Dermatology/
	following expanded		incision, excision,	lymph vessels and	Plastic Surgery:
	Indications for Use:		vaporization and	nodes, organs and	Indications
			coagulation of	glands. Surgical	include, epidermal
	Dermatology/Plastic		soft tissue during	specialties and	nevi,
	Surgery:		general surgical	applications include	telangiectasia,
			applications	general surgery,	spider veins,

Descriptive	Waterlase iPlus S	Oculase MD	Waterlase MD	Profile Multi-	Laserscope VELA
Information		(K052354)	Derm	Platform System	(K971843)
			(K071734)	(K060033)	
	Incision, excision,		where skin	plastic surgery,	actinic cheilitis,
	ablation, vaporization		incision, tissue	aesthetic surgery,	keloids, verrucae,
	and coagulation of		dissection,	dermatology,	skin tags, anal
	dermatologic tissues		excision of	urology, gynecology,	tags, keratoses,
	including epidermal		external tumors	genitourinary, ENT,	scar revision,
	nevi, telangiectasia,		and lesions,	pulmonary, surgery,	debulking benign
	spider veins, actinic		complete or	thoracic surgery,	tumors, decubitis
	cheilitis, keloids,		partial resection	podiatry, oral &	ulcers and skin
	verrucae, skin tags, anal		of internal organs,	maxillofacial	resurfacing.
	tags, keratoses, scar		tumors and	surgery,	General Surgery
	revision, debulking of		lesions, tissue	ophthalmology	The Erbium:YAG
	benign tumors,		ablation and/or	(including	laser is intended
	decubitis ulcers, cysts,		vessel coagulation	oculoplasty), small	for the surgical
	diagnostic biopsy and		may be indicated.	and large joint	incision/excision,
	skin resurfacing and			arthroscopy, micro-	vaporization and
	treatment of wrinkles.			discectomies and	coagulation of soft
				endoscopic	tissue during any
	Ear, Nose and Throat			procedures.	general surgery
	(ENT):			Aesthetic Surgery	application where
	ENT surgery in soft,			Skin resurfacing and	skin incision,
	mucosal, cartilaginous			treatment of	tissue dissection,
	and bony tissue,			wrinkles.	excision of
	including endosinus			Dermatology &	external tumors
	surgery, functional			Plastic Surgery	and lesions,
	endoscopic sinus			Indications include,	complete or
	surgery, turbinate			epidermal nevi,	partial resection
	procedures (e.g.			telangiectasia,	of internal organs,
	turbinoplasty,			spider veins, actinic	tumors and
	turbinectomy),			cheilitis, keloids,	lesions, tissue

Descriptive	Waterlase iPlus S	Oculase MD	Waterlase MD	Profile Multi-	Laserscope VELA
Information		(K052354)	Derm	Platform System	(K971843)
			(K071734)	(K060033)	
	dacryocystorhinostomy			verrucae, skin tags,	ablation and/or
	(DCR), ethmoidectomy,			anal tags, keratoses,	vessel coagulation
	polypectomy, maxillary			scar revision,	may be indicated.
	antrotomy, frontal			debulking benign	Genitourinary:
	sinusotomy,			tumors, decubitis	Indications
	sphenoidotomy,			ulcers. It is also	include lesions of
	hereditary hemorrhagic			used for laser	the external
	telangiectasias,			assisted site	genitalia, urethra
	septoplasty, lesions,			preparation for hair	and anus, penis,
	polyps, cysts,			transplantation.	scrotum and
	hyperkeratosis, excision			<u>Gastroenterology</u>	urethra (includes
	of carcinogenic tissue,			Gastroenterologic	condyloma
	oral leukoplakia.			surgery of soft	acuminate, giant
				tissue, include:	perineal
	Gastroenterology:			cholecystectomy,	condyloma and
	Gastroenterologic			lysis of adhesions,	verrucous
	surgery of soft tissue,			appendectomy,	carcinoma), vulvar
	including			biopsy,	lesions, polyps
	cholecystectomy, lysis			pylorostenotomy,	and familiar
	of adhesions,			benign and	polyps of the
	appendectomy, biopsy,			malignant lesions,	colon.
	pylorostenotomy,			rectal polyps of	<u>Gynecology</u>
	benign and malignant			sigmoid colon, gall	Indications
	lesions, rectal polyps of			bladder calculi,	include cervical
	sigmoid colon, gall			biliary/bile duct	intraepithelial
	bladder calculi,			calculi, benign and	neoplasia (CIN),
	biliary/bile duct calculi,			malignant	herpes simplex,
	benign and malignant			neoplasm, polyps,	endometrial
	neoplasm, polyps,			colitis, ulcers,	

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
	colitis, ulcers,		(coor and sy	angiodysplasia,	adhesions, cysts
	angiodysplasia,			hemorrhoids,	and condyloma.
	hemorrhoids, varices,			varices, esophagitis,	<u>ENT</u>
	esophagitis, esophageal			esophageal ulcer,	Indications
	ulcer, Mallory-Weiss			Mallory-Weiss tear,	include ear, nose
	tear, gastric ulcer,			gastric ulcer,	and throat lesions,
	duodenal ulcer, non-			duodenal ulcer,	polyps, cysts,
	bleeding ulcer, gastric			non-bleeding ulcer,	hyperkeratosis,
	erosions, colorectal			gastric erosions,	excision of
	cancer, gastritis,			colorectal cancer,	carcinogenic
	bleeding tumors,			gastritis, bleeding	tissue, oral
	pancreatitis, vascular			tumors,	leukoplakia.
	malformations,			pancreatitis,	Oral/Maxillofacial
	telangiectasias and			vascular	Indications
	telangiectasias of the			malformations,	include benign
	Osler-Weber-Rendu			telangiectasias and	oral tumors, oral
	disease.			telangiectasias of	and glossal lesions
				the Osler-Weber-	and gingivectomy.
	General Surgery:			Rendu disease.	<u>Ophthalmology</u>
	Incision, excision,			General Surgery	Indications
	vaporization and			The Er:YAG is	include soft tissue
	coagulation of soft			intended for the	surrounding the
	tissue during general			surgical	eye and orbit and
	surgical applications			incision/excision,	anterior
	where skin incision,			vaporization and	capsulotomy.
	tissue dissection,			coagulation of soft	<u>Podiatry</u>
	excision of external			tissue during any	Indications
	tumors and lesions,			general surgery	include warts,
	complete or partial			application where	plantar verrucae,

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm	Profile Multi- Platform System	Laserscope VELA (K971843)
			(K071734)	(K060033)	
	resection of internal			skin incision, tissue	large mosaic
	organs, tumors and			dissection, excision	verrucae and
	lesions, tissue ablation			of external tumors	matrixectomy.
	and/or vessel			and lesions,	
	coagulation may be			complete or partial	
	indicated.			resection of internal	
				organs, tumors,	
				tissue ablation	
	Genitourinary/Urology:			and/or vessel	
	Genitourinary surgery of			coagulation.	
	soft tissue, including			Genitourinary/	
	treatment of bladder,			<u>Urology</u>	
	urethral and ureteral			Genitourinary	
	tumors, superficial			surgery of soft	
	urinary bladder tumors,			tissue, including:	
	invasive bladder			treatment of	
	carcinomas, urethral			bladder, urethral	
	and penile			and ureteral	
	hemangioma, urethral			tumors; superficial	
	strictures, lesions of the			urinary bladder	
	external genitalia,			tumors; invasive	
	urethra and anus, penis,			bladder carcinomas;	
	scrotum, (includes			urethral and penile	
	condyloma acuminate,			hemangioma;	
	giant perineal			urethral strictures,	
	condyloma and			lesions of the	
	verrucous carcinoma),			external genitalia;	
	vulvar lesions, polyps			condylomas;	
	and familial polyps of				

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
	the colon, bladder neck		(1101 210 1)	bladder neck	
	obstructions.			obstructions.	
	Endoscopic			Endoscopic	
	transurethral incision of			transurethral	
	prostate, bladder neck			incision of prostate,	
	incision of the prostate,			bladder neck	
	laser ablation,			incision of the	
	enucleation and			prostate, laser	
	resection of prostate,			ablation,	
	hemostasis,			enucleation and	
	vaporization and			resection of	
	excision for treatment			prostate,	
	of benign prostatic			hemostasis,	
	hypertrophy.			vaporization and	
	Gynecology:			excision for	
	Cervical intraepithelial			treatment of benign	
	neoplasia (CIN), herpes			prostatic	
	simplex, endometrial			hypertrophy.	
	adhesions, cysts and			<u>Gynecology</u>	
	condyloma.			Indications include	
				cervical	
	Ophthalmology:			intraepithelial	
	General ophthalmic soft			neoplasia (CIN),	
	tissue surgical			herpes simplex,	
	indications such as:			endometrial	
	Incision, excision,			adhesions, cysts and	
	vaporization and			condyloma.	
	coagulation of ocular			<u>Ophthalmology</u>	
	tissue and tissue				

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
	surrounding the eye and			Indications include	
	orbit.			soft tissue	
	Oral/Maxillofacial			surrounding the eye	
	Surgery:			and orbit and	
	Oral/dental procedures			anterior	
	for incision, excision,			capsulotomy.	
	ablation, vaporization			Oral/	
	and hemostasis of soft			<u>Maxillofacial</u>	
	tissue during			Indications include	
	gingivoplasties,			oral/dental	
	gingivectomies,			procedures for	
	frenectomies, benign			incision, excision,	
	and malignant lesion			ablation,	
	removal, biopsies,			vaporization and	
	leukoplakia and			hemostasis of soft	
	fibrotomy.			tissue during	
				gingivoplasties,	
	Podiatry:			gingivectomies,	
	Warts, plantar verrucae,			frenectomies,	
	large mosaic verrucae			benign and	
	and matrixectomy.			malignant lesion	
	· ·			removal, biopsies,	
	Pulmonary Surgery:			leukoplakia and	
	Open and endoscopic			fibrotomy.	
	pulmonary surgery.			ENT Surgery	
				ENT surgery in soft,	
	Thoracic Surgery:			mucosal,	
	Surgical			cartilaginous and	
	incision/excision,			bony tissue,	

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
	vaporization and			including: endosinus	
	coagulation of soft			surgery, functional	
	tissue during any			endoscopic sinus	
	thoracic surgery.			surgery, turbinate	
				procedures (e.g.	
				turbinoplasty,	
				turbinectomy),	
				dacryocysto-	
				rhinostomy (DCR),	
				ethmoidectomy,	
				polypectomy,	
				maxillary	
				antrotomy, frontal	
				sinusotomy,	
				sphenoidotomy,	
				hereditary	
				hemorrhagic	
				telangiectasia,	
				septoplasty.	
				<u>Podiatry</u>	
				Indications include	
				warts, plantar	
				verrucae, large	
				mosaic verrucae and	
				matrixectomy.	
				Pulmonary Surgery	
				Open and	
				endoscopic	
				pulmonary surgery.	

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
				Thoracic Surgery Intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.	
Laser Classification	IV (4)	IV (4)	IV (4)	IV (4)	IV (4)
Operating Voltage	100 VAC ± 10% 230VAC ± 10%	100 VAC ± 10% 230VAC ± 10%	100 VAC ± 10% 230VAC ± 10%	200 - 240 VAC	220 VAC
Laser Medium	ER,CR:YSGG	ER,CR:YSGG	ER,CR:YSGG	ER:YAG	ER:YAG
Wavelength	2.78μm (2780nm)	2.78µm (2780nm)	2.78μm (2780nm)	2940nm	2940nm
Current Frequency	50 - 60 Hz	Not available			
Max Output Power	10 watts ± 20%	8 watts ± 20%	8 watts ± 20%	45 watts ± 20%	45 watts
Power Mode	Pulsed Free Running	Pulsed Free Running	Pulsed Free Running	Not available	Not available
Cooling	Water	Water	Water	Not available	Not available
Pulse Duration	60μs, 700μs	60μs, 700μs	60μs, 700μs	100 μs - 5ms	Not available
Aiming Beam	Laser Diode, max 1mW, 635nm Class I	Laser Diode, max 1mW, 635nm Class I	Laser Diode, max 1mW, 635nm Class I	Laser Diode, max 5mW, 650nm ± 5nm Class II	Not available

Descriptive Information	Waterlase iPlus S	Oculase MD (K052354)	Waterlase MD Derm (K071734)	Profile Multi- Platform System (K060033)	Laserscope VELA (K971843)
	Medical grade plastics,	Medical grade	Medical grade	Medical grade	Medical grade
	steel, stainless steel,	plastics, steel,	plastics, steel,	plastics, steel,	plastics, steel,
	aluminum, brass, and	stainless steel,	stainless steel,	stainless steel,	stainless steel,
Materials	electronic parts and	aluminum, brass,	aluminum, brass,	aluminum, brass,	aluminum, brass,
	components	and electronic parts	and electronic	and electronic parts	and electronic
		and components	parts and	and components	parts and
			components		components

Non-Clinical Test Data

Safety testing of the *Waterlase iPlus S* was successfully completed according to IEC 60601-1 – Medical electrical equipment, Part 1: General requirements for safety and essential performance, IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance –collateral standard: electromagnetic compatibility- requirements and tests, IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements, IEC 60601-2-22 Medical electrical equipment- Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

Software verification and validation was conducted due to modifications of layout of the Graphical User Interface resulting from the expanded indications for use. The results demonstrate that the *Waterlase iPlus S* performs according to specifications and functions intended.

No other performance testing was conducted since the purpose of this 510(k) is to only expand the Indications for Use from the previous 510(k) clearances under 510(k) Nos.: K101658 and K122368. All indications included in this 510(k) have already been cleared by the FDA for equivalent medical devices manufactured by Biolase, Inc., Sciton, Inc. and Laserscope.

Clinical Test Data

Clinical testing was not conducted on this device.

Conclusion

Based upon the comparison of the *Waterlase iPlus S* with the same device, *Waterlase iPlus, Profile Multi-Platform System* and *Laserscope VELA* previously cleared by the FDA, the clinical performance of the *Waterlase iPlus S* for the Indications for Use described above is deemed to be substantially equivalent to the legally-marketed predicate devices, the *Waterlase iPlus, Profile Multi-Platform System* and *Laserscope VELA*.